REMARKS

Claims 32, 41, and 49 have been amended herein, but no new matter has been added. Reconsideration of the present Application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 102(b)

Claims 32-52 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kobrinski, et al. (*Biomedical Engineering*, Vol. 31, No. 3, p. 172-174) ("Kobrinski"). Such a rejection is improper in view of the amendments made herein for, at least, the following reasons.

For a claim to be anticipated, "each and every element as set forth in the claim" must be found "either expressly or inherently described, in a single prior art reference." MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the . . . claim." MPEP § 2131 (quoting *Richardson Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In other words, to anticipate a claim, a reference must teach each and every element of a claim in as complete detail as the claim recites the elements.

Independent claim 32, as amended herein, is directed to a computer-implemented method for determining and presenting the likelihood a person has a mutated form of a gene. The method comprises receiving an electronic order for at least one of a clinical agent or a clinical event from a clinician. In response to the order for at least one of the clinical agent or the clinical event, claim 32 further recites determining whether the at least one of the clinical agent or the clinical event is associated with a gene. If the at least one of the clinical agent or the clinical event is associated with the gene, a first database is queried to determine whether the

person has one or more genetic test results for the gene. The method also comprises obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene and querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. The one or more genetic test results of the at least one family member are utilized to "automatically" calculate a likelihood the person has a mutated form of the gene if at least one of the family members has genetic test results for the gene. The calculated likelihood the person has a mutated form of the gene is presented to the clinician. Applicants submit no new matter has been added by way of these amendments. *See Specification*, ¶¶ 0030-0032 and 0065-0066.

Kobrinski fails to teach the same. Instead, Kobrinski describes a computerized system configured to exchange information between regional and interregional medical genetic consultations and centers. *See Kobrinski* at para. 1, p. 172. At best, Kobrinski discloses a system that stores medical documentation and can be configured to apply mathematical models for calculating the risk of genetic diseases. *See id.* at para. 2, 5, and 7. However, Kobrinski does not describe a system that: (1) receives "an electronic order for at least one of a clinical agent or a clinical event from a clinician," and (2) "in response to receiving the at least one of the clinical agent or the clinical event, determining whether the at least one of the clinical agent or the clinical event is associated with one or more genetic test results."

Furthermore, claim 32, as amended herein, recites receiving a request for an electronic order for a patient and automatically returning different information (the patient's likelihood of having a gene mutation). The mathematical models described in Kobrinski merely calculate the risk of genetic disease. No mention is made in Kobrinski of "automatically" calculating a likelihood for gene mutation based on a received electronic order from a clinician – as recited in amended claim 32.

For at least the above reasons, Kobrinski does not describe each and every element of claim 32. Accordingly, it is submitted that the § 102(b) rejection thereto is improper, and Applicants respectfully request its withdrawal.

Independent claim 41 is directed to a computer system for determining and presenting the likelihood a person has a mutated form of a gene. The computer system comprises a receiving module for receiving "an electronic order for at least one of a clinical agent or a clinical event for a person from a clinician" and a determining module for "determining whether the at least one of the clinical agent or the clinical event is associated with a gene." A first querying module is configured to query a first database to determine if the person has one or more genetic test results for the gene in response to the electronic order by the clinician "if the at least one of the clinical agent or the clinical event is associated with one or more genetic test results." The system further comprises an obtaining module for obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene and a second querying module for querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. A utilizing module utilizes the one or more genetic test results of the at least one family member to "automatically" calculate a likelihood the person has a mutated form of the gene if at least one of the family members has genetic test results for the gene. A presenting module presents the calculated likelihood the person has a mutated form of the gene to the clinician. In other words, claim 41 recites several modules that are configured to carry out various aspects of claim 32. Applicants submit no new matter has been added by way of these amendments. *See Specification*, ¶¶ 0030-0032 and 0065-0066.

Kobrinski fails to teach the same. As previously stated, Kobrinski discloses a system that stores medical documentation and can be configured to apply mathematical models for calculating the risk of genetic diseases. *See Kobrinski* at ¶¶ 2, 5, and 7. But it does not describe "a receiving module for receiving an electronic order for at least one of a clinical agent or a clinical event for a person from a clinician," a determining module for "determining whether the at least one of the clinical agent or the clinical event is associated with a gene," or a first querying module for querying a database to determine if the person has one or more genetic test results for the gene in response to the electronic order by the clinician "if the at least one of the clinical agent or the clinical event is associated with one or more genetic test results." Nor does Kobrinski describe "automatically" calculating a likelihood the person has a mutated gene; instead, Kobrinski describes "automatic analysis of genealogical trees." *See Kobrinski* at ¶ 8, p. 172. In Kobrinski, the analysis is not triggered by a clinical agent or event being associated with a genetic test result. Moreover, Kobrinski describes using mathematical models to calculate the risk of genetic disease for a patient, but such a calculation is not automatically performed after a determination is made that the patient does not have gene-mutation test results. Thus, neither the receiving, determining, or utilizing modules of claim 41, as amended herein, are described in Kobrinski.

Therefore, Kobrinski fails to disclose each and every element of claim 41, as amended herein. Accordingly, it is submitted that the § 102(b) rejection thereto is improper, and Applicants respectfully request its withdrawal.

Independent claim 49 is directed to a method for determining and presenting the likelihood a person has a mutated form of a gene. The method comprises receiving from a clinician "an order for medication" for a person and, in response to receiving the order for medication, "determining whether the order for medication is associated with a genetic finding."

A database is queried to determine if the person has one or more genetic test results for the gene "in response to the order." Also, the mode of inheritance for the gene is obtained "if the person does not have one or more genetic test results for the gene." A second database is queried "to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene." If the patient does not have genetic test results for the gene, a determination is made as to whether inferred results are allowed for the gene, and if so, "an inferred finding that the patient has a mutated form of the gene" is automatically calculated "based, in part, on one or more genetic findings associated with one or more family members of the patient." This inferred finding is eventually presented to a clinician. Applicants submit that no new matter has been added by way of these amendments. *See Specification*, ¶¶ 0030-0032, 0034-0037, and 0065-0066.

Kobrinski fails to teach the same. Instead, Kobrinski describes a computerized system configured to exchange information between regional and interregional medical genetic consultations and centers. *See Kobrinski* at ¶ 1, p. 172. At best, Kobrinski discloses a system that stores medical documentation and can be configured to apply mathematical models for calculating the risk of genetic diseases. *See id.* at ¶¶ 2, 5, and 7. However, Kobrinski does not describe a system that: (1) receives "an order for medication" from a clinician, (2) determines whether the order for medication is "associated with a gene," and (2) determines if a person has genetic test results for the gene "in response to the order." Nor does Kobrinski determine whether inferred results are allowed for a particular gene, let alone automatically calculating an inferred finding based on the genetic findings associated with the patient's family members.

For at least the previously stated reasons, Kobrinski does not describe each and every element of claim 49, as amended herein. Accordingly, it is submitted that the § 102(b) rejection thereto is improper, and Applicants respectfully request its withdrawal.

Additionally, dependent claims 33-40, 42-48, 50, and 51 are also in condition for allowance based at least in part on their dependence, either directly or indirectly, from one of independent claims 32, 41, and 49. Accordingly, Applicants respectfully request withdrawal of the § 102(b) rejections thereto.

Rejections based on 35 U.S.C. § 103(a)

Claims 32-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pathak et al. (Proceedings of the Tenth Conference on Artificial Intelligence for Applications)(referred to herein as "Pathak").

To establish a *prima facie* case of obviousness, the prior-art references must teach or suggest all the claim limitations. *See* MPEP § 2143. Furthermore, the teaching or suggestion, and the reasonable expectation of success must be found in the prior art and not be based on the Applicants' disclosure. MPEP § 2143 (referencing *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991)). The Supreme Court in *Graham v. John Deere*, 383 U.S. 1 (1966) declared that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *See Graham v. John Deere Co.*, To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham v. John Deere* and to provide some reason to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention.[1] On pages 13-14 of the recent Supreme Court case, *KSR v. Teleflex*, the Supreme Court clarified the requirements necessary before references can be combined to support an obviousness rejection.

> Often, it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and

[1] *See*, *Application of Bergel,* 292 F. 2d 955, 956-957 (1961).

> the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application].

KSR v. Teleflex, No. 04-1350, 127 S.Ct. 1727 (2007).

With respect to independent claims 32, 41, and 49, as discussed above, Pathak does not teach or suggest receiving an electronic order from a clinician for either a clinical agent or a clinical event for a person (as recited in amended claim 32 above) or orders for medication (as recited in amended claim 49 above) for a person. Further, Pathak does not teach or suggest determining whether the clinical agents or events or orders for medication are associated with genetic test results "in response to receiving" the agent, event, or order. Nor does Pathak teach or suggest modules configured to perform all these functions.

To the contrary, Pathak describes calculating genetic risks, which it defines as the probability that patients may either develop a genetic disorder or transmit a genetic disease to their children. *See Pathak*, Introduction, p. 164. These risks are not automatically calculated in response to a clinician's order for clinical agents (such as medications) or events, as recited in claims 32, 41, and 49, as amended herein.

The Office stated that "Pathak et al does not teach risk of atypical events" as recited in dependent claims 37, 38, 46, 47, 51, and 52. *Office Action*, p. 8. Rather than pointing to specific information in Pathak or other prior references that suggest the combination of Pathak with the ability to calculate a risk of atypical events, the Office has supplemented this feature *sua sponte*. Nowhere does the Office particularly identify any suggestion or teaching, such as the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness

analysis.[2] Because no specific art or documentary evidence is referenced to support this assertion; as such, the Office has taken "Official Notice" and based the § 103(a) rejection on general skill in the art.

The Office opined that the methods and systems recited in these dependent claims would be obvious in light of Pathak because "a clinician would want to know what the probability is that a mutation is linked or correlated with an event that is not typical for the condition and because the method/sysem of Pathak et al is modular ([Pathak]p. 169, col 2, para 1)." The Office further explained its conclusion to take official notice of portions of features of claims 37, 38, 46, 47, 51, and 52 directed to atypical events.

> Further, it would be obvious for a clinician to inquire the risk associated with having an adverse reaction to a prescribed treatment. This is a function that every clinician performs each time a treatment for a condition is prescribed. For example, such as queries related to allergies to specific antibiotics like sulfadrugs or to particular general anesthetics. As with treatment, it is common sense that a clinician would first determine if a condition exists in a patient through examination, diagnosis tests in order to prescribe potential modes of treatment, then consults (queries) the family history for previous instances of the condition under a defined genetic background. After considering the family history, the clinician then determines given the genetic background of the patient which prescribed mode of treatment yields the lowest risk of adverse reaction. The limitation of querying the patient record/database and the family history record/database upon prescription of medication merely automates a common process of the medical arts and is therefore obvious.

Id.

Moreover, official notice without documentary evidence is permissible only in limited circumstances to support an examiner's conclusion. *See MPEP* § 2144.03 (A). "It would not be appropriate for the examiner to take official notice of facts without citing a prior art

[2] *See, e.g., Pro-Mold & Tool*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." *Id.* (emphasis in original). "To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." MPEP § 2144.03 (C).

Applicants respectfully submit that the Office erred in taking official notice. The Office's conclusory statements about the general practice of physicians does not teach or describe a system or method configured to recognize atypical events. Sure, physicians ask questions about what ails their patients; however, they do not query computer databases to determine whether any information stored therein indicates an atypical event. Nor do physicians access databases detailing genetic findings of family members; at best, physicians may review a patient's medical chart, which may or may not contain genealogical information.

Moreover, physicians think of information they have previously read and simply apply the specific facts of a patient thereto. However, if the physician forgets something he/she read or misinterprets the facts, a different conclusion may be reached. Whereas, claims 37, 38, 46, 47, 51, and 52 recite embodiments of the present invention where information is stored and accessible without being dependent on a person's memory.

Therefore, it is respectfully submitted that the general operations of physicians does not teach or suggest the calculation of risks for atypical events, as recited in claims 37, 38, 46, 47, 51, and 52. Also, asserting that a physician actually calculates risks of atypical events in the same manner as the recited claims (i.e., accessing several databases storing personal and genealogical genetic testing information) is not present in the Office's line of reasoning, which merely states a physician simply asks a patient questions about their health. Accordingly, Applicants submit that the official notice taken in the Final Office Action was improper and does

not teach or suggest the features of the present invention directed to calculating risk of atypical events.

In conclusion, Pathak fails to teach or suggest all of the features of claims 32, 41, and 49, as amended herein. Accordingly, these claims are believed to be in condition for allowance, and Applicants respectfully request withdrawal of the § 103(a) rejection thereto. In addition, dependent claims 33-40, 43-48, 51, and 52 should be allowed based in part on their dependence, either directly or indirectly, from one of claims 32, 41, or 49. *See* MPEP § 2143.03; *see also, In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988) ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.").

CONCLUSION

Applicants submit that new claims 32-52, as amended herein, are in condition for allowance. If any issues remain that would prevent issuance of this Application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action. The Commissioner is hereby authorized to charge any additional amount required (or credit any overpayment) to Deposit Account No. 19-2112.

Respectfully submitted,

/Peter J. Hoeller/

Peter J. Hoeller
Reg. No. 61,468

PJH/cn
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108-2613
816-474-6550